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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,078	07/01/2003	John S. Patton	0005.16	6971

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NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,078	PATTON ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,28-31 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,28-31 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7-28-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 6-10-05 is acknowledged.

Claims included in the prosecution are 26, 28-31 and 33-35.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 26, 28-31 and 33-35 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim14-18 of U.S. Patent No. 6,685,967. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims and instant claims recite the same insulin composition; patented claims recite in addition, "moisture content below 10 %. Since this expression includes even 0 %, meaning that the compositions contain no moisture at all, instant claims, which recite no moisture limitations at all, therefore, anticipate the patented compositions.

Applicants indicate their willingness to file the terminal disclaimer. This rejection is maintained in abeyance.

3. Claims 26, 28-31 and 33-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 28-41, 43-49 and 51--57 of copending Application No. 10/141,044. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both copending application and instant application are drawn to the same insulin powder composition. Instant claims are generic with respect to the buffer and the claims in the copending application recite citrate buffer. Instant dependent claim 30 recites citrate. It would have be obvious to one of ordinary skill in the art to choose an appropriate buffer to maintain the pH of the medium at which insulin maintains its biological activity without degradation. The claims in the copending application recite specific insulin amounts. Instant claims are generic with respect to insulin amounts and it would have been obvious to one of ordinary skill in the art to vary the insulin amounts and obtain the desired amounts since it depends upon the amounts of the salts present in the buffer solution and other carriers added.

4. Claims 26, 28-31 and 33-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-34, and 39-43 of copending Application No. 10/612,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both copending application and instant application are drawn to the same insulin powder composition. Instant claims are product by process claims reciting insulin in amounts of 15-80 %, particles sizes of 01 micrometer to 5 micrometers and an aqueous buffer in a specific concentration. Claims in the copending application recite insulin amounts of 20-

80 %, sizes of less than 10 microns. The overlapping ranges anticipate each other. Instant sizes are anticipated by 'below 10' limitation in the claims of the copending application. Claim 39 in the copending application recites in addition a moisture content below 10 % which implies even 0 moisture content and instant claims which recite no moisture content thus anticipate the copending claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 26, 28-29 and 31, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz cited above.

Platz's disclosure relates to inhalation therapy involving the administration of a drug in aerosol from to the respiratory tract. According to Platz, "the present invention is useful for transforming polypeptide drugs into a powder form that is suitable for aerosol administration (col. 2, lines 13-15). Examples of such polypeptides include, inter alia,

insulin (col. 2, line 21). The dry powder compositions further include pharmaceutical carriers such as lactose and trehalose (col. 2, line 51). Platz discloses a two-step where the first step in the process for forming the polypeptides into micronized particles is lyophilization of buffer solution (col. 2, lines 38-40; col. 6, lines 4-5). Subsequently, the lyophilized polypeptide is size reduced in a grinding mill, preferably a fluid energy mill also known as a jet mill (col. 3, lines 3-5). The particle size of the milled powder disclosed by Platz appears to be essentially the same as the particle sizes recited in instant claims (Platz, col. 3, line 65 through col. 4, line 19). Thus, it would appear that Platz discloses a stable, dry powder insulin composition containing amorphous particles having a particle size essentially the same as the particle size recited in claim 26 (see also instant specification, page, 9, lines 20-31, in this regard). The burden is therefore, upon applicant to show that instant particles are patentably distinct from those disclosed by Platz. Assuming that they are different since Platz is directed to the same inhalation therapy using particles of insulin, it is deemed obvious to manipulate the teachings of Platz that is using spray drying instead of lyophilization to obtain the best possible particles.

Applicant's arguments have been fully considered, but are not found to be persuasive. First of all, it should be pointed out that the examiner s response in the prior art is incorporated in this action. In response to the examiner's position that since Platz on col. 4, lines 44-45 teaches that the amounts of the bulking agents normally constitute about 50 to 99.99 % which implies that rest could be the active agent, applicant argues that the examiner does not recognize that components other than the active agent and

the bulking agent are present in the powders of Platz et al. In support, applicant points out to Example 2 and argues that human serum albumin and NaCl are present in ' significantly larger quantities than the active agent. This argument is not found to be persuasive. There is nothing in Platz to indicate that human serum albumin and NaCl are 'components other than active agent' and not bulking agents. Therefore, the examiner still holds the position that Platz's teachings of 50 to 99.99 % bulking agents could still imply that the rest could be the active agent. Furhermore, as applicants themselves state that Platz teaches the administration of the active agent 'neat'. Based on this teaching by Platz, that is 100 DA active agent can be administered as such and based also on Platz that 50 to 99.00 % bulking agent could be used it would be prima facie obvious to one of ordinary skill in the art that the amounts of the active agent and the bulking agent can be varied.

7. Claims 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz cited above, in combination with Chien (5,042,975) also of record.

The teachings of Platz have been discussed above. What is lacking in Platz is the teaching of the use of citrate as the buffer for insulin. Such a use however, would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success, since Chien teaches that citrate is a commonly used buffer in combination with insulin (example 3 on col. 17).

Applicant's arguments have been fully considered, but are not found to be persuasive. Arguments regarding Platz have been addressed above. Applicant provides no specific arguments regarding Chien. The rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK